



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1563]

Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: On January 16, 2013, the Food and Drug Administration (FDA) announced the availability of, and requested comment on, a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA). FDA is now announcing the availability of, and requesting comment on, a document entitled "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA Appendix). The purpose of the draft RA Appendix is to provide a science-based risk analysis of those foods whose production would be considered low risk with respect to the risk of intentional adulteration caused by acts of terrorism. The appendix supplements the science-based risk analysis already included in the draft RA, which does not consider the risk of intentional adulteration caused by acts of terrorism. FDA conducted this evaluation to satisfy requirements

of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

DATES: Submit either electronic or written comments on the draft RA Appendix by March 31, 2014.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-3712.

SUPPLEMENTARY INFORMATION:

I. Background

On January 4, 2011, FSMA (Public Law 111-353) was signed into law. Section 103 of FSMA, Hazard analysis and risk-based preventive controls, amends the FD&C Act to create a new section 418 with the same name. Section 418 of the FD&C Act (21 U.S.C. 350g) contains requirements applicable to food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and mandates Agency rulemaking. Section 418(a) of the FD&C Act is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) of the FD&C Act specifies that the purpose of the preventive controls is to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342)

or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). Section 418(b) of the FD&C Act requires that the hazard analysis identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism. Sections 418(c) through (i) of the FD&C Act contain additional requirements applicable to facilities, including requirements for preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). On January 16, 2013, FDA issued a proposed rule (the proposed preventive controls rule for human food) to implement section 418 of the FD&C Act for human food with respect to hazards other than intentional adulteration (78 FR 3646). Elsewhere in this issue of the Federal Register, FDA is issuing a proposed rule entitled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" (hereafter, the Intentional Adulteration proposed rule) to implement section 418 of the FD&C Act with respect to intentional adulteration caused by acts of terrorism.

Among other things, section 103(c) of FSMA requires FDA to consider possible exemption from or modification of requirements of section 418 and section 421 (U.S.C. 350j) (Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report) of the FD&C Act for certain facilities as FDA deems appropriate.

Section 103(c)(1)(C) of FSMA directs the Secretary of Health and Human Services (the Secretary) to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover: (1) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods and (2) specific on-farm manufacturing and

processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

Section 103(c)(1)(D)(i) of FSMA requires that the Secretary consider the results of the science-based risk analysis, and exempt certain facilities from the requirements in section 418 of the FD&C Act (including requirements related to intentional adulteration), and the mandatory inspection frequency in section 421 of the FD&C Act, or modify the requirements in sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk. Section 103(c)(1)(D)(ii) of FSMA provides, in relevant part, that the exemptions or modifications described in section 103(c)(1)(D)(i) shall apply only to small businesses and very small businesses, as defined in the regulation issued under section 418(n) of the FD&C Act.

II. Qualitative Risk Assessment and Appendix

On January 16, 2013, the Food and Drug Administration (FDA) announced the availability of, and requested comment on, a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA) (78 FR 3824).

We conducted the qualitative risk assessment to identify activity/food combinations that would be considered low risk for human foods with respect to hazards that may be unintentionally introduced to the food (Ref. 1).

FDA is now announcing the availability of, and requesting comment on, a document entitled "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located

on a Farm" (the draft RA Appendix) (Ref. 2). The purpose of the draft RA Appendix is to provide a science-based risk analysis of those foods whose production would be considered low risk with respect to the risk of intentional adulteration caused by acts of terrorism. The appendix supplements the science-based risk analysis already included in the draft RA, which does not consider the risk of intentional adulteration caused by acts of terrorism. In the Intentional Adulteration proposed rule, FDA is considering using the results of this evaluation to exempt, or modify requirements for, food facilities that are small or very small businesses that are engaged only in specific types of on-farm food production identified in the draft RA Appendix as low-risk with respect to intentional adulteration caused by acts of terrorism.

In both risk assessments, we focused on food types produced on farms. When considering intentional adulteration, however, we considered the overall production practices for various types of finished foods rather than separating manufacturing, processing, packing, and holding activities (Ref. 2). This reflects the different analysis for "low risk" we used to evaluate the risk of hazards that may be intentionally introduced by acts of terrorism as compared to determining "low risk" for other hazards in the draft RA. In the draft RA Appendix, we describe the approach applied to identify low-risk production processes and to determine food types out of the scope of the draft RA Appendix, and to evaluate hazards associated with foods within the scope of the draft RA Appendix (Ref. 2).

We are seeking comments that can be used to improve: (1) the approach used, (2) the assumptions made, (3) the data used, and (4) the transparency of the draft RA Appendix. Specifically we request comment on: (1) the criteria for identifying a "low-risk production process," and the approach to characterizing the risk of specific food production processes, including whether there are other ways in which we could further focus on foods that present a

high risk of intentional adulteration caused by acts of terrorism. For example, whether there are ways in which a food's shelf life, turnover in the marketplace, batch size, serving size and servings per batch, distribution and consumption patterns and intended consumer could be considered and (2) the food types that we are considering outside the scope of the draft RA Appendix and those we are considering within the scope of the draft RA Appendix.

We will consider public comments regarding the draft RA Appendix in preparing a final version of the RA Appendix and the Intentional Adulteration rule.

III. Comments

Interested persons may submit either electronic comments regarding the draft RA Appendix to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

The draft RA Appendix is available electronically at <http://www.regulations.gov> and at <http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM377408.pdf>.

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not

responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. FDA, "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2012. Available at:

<http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM334110.pdf>.

2. FDA, "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2013. Available at:

<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM377408.pdf>.

Dated: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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